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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,979	02/12/2001	Parula Mehta	98,375-C	1569
20306	7590	11/18/2003	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE SUITE 3200 CHICAGO, IL 60606			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,979	MEHTA ET AL	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-27-2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1, 2, and 4-12 are pending and under consideration. Claims 1-9 were rejected in the Final Office action mailed on April 21, 2003 (the prior action). In the response to that action, filed an After Final amendment on October 27, 2003 (the Response). In that Response, the Applicant amended claim 1, and new claims 13.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **(Prior Rejection- Restated and Maintained)** Claims 1,2, and 4-12 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over McCormick (U.S. Patent 3,431,886) in view of Copeland (U.S. Patent 5,650,327), and in view of McManus et al. (Staining Methods, Histologic and Histochemical, Paul B. Hoeber, Inc., New York, 1960. The claims read on automated methods of staining biological materials on a slide comprising providing a first and second unstable solution, and providing a slide with a biological material to be stained, and sequentially applying the first and second solutions to the material such that an

Art Unit: 1648

unstable solution is formed in contact with the material. Currently pending claims 1, 2, and 4-13 are rejected as obvious over the teachings of McCormick in view of Copeland and McManus, and in light of the teachings of Stokes et al. (U.S. Patent 5,318,795).

As indicated in the prior actions, McCormick teaches an automated method for staining biological materials on a slide. This method comprises steps of providing a plurality of staining solutions (col. 2, lines 6-17), providing a slide having biological materials (col. 1, lines 36-45), providing an automated delivery system to deliver a predetermined amount of the staining solutions to the slide, and sequentially applying the staining solutions to the slide (col. 2, lines 18-40). McCormick does not teach mixing the reagents on the slide by applying at least two gas streams to form a vortex, as in the present invention.

Copeland teaches an automated method for staining tissue sections mounted on slides (col. 1, lines 15-20). This automated methods comprises a step of applying a reagent staining solution to the slide and mixing the solution on the surface of the slide containing the tissue by applying a gas steam or two gas streams so as to form a vortex (col. 4, lines 35-50). The reference does not specifically teach that the staining reagent being mixed is a stable stain resulting from the mixing of two or more unstable reagents. It is the Examiner's position that, given that such stains are known in the art as evidenced by McManus, and by the Applicant's description of conventional stains in the art (see e.g., App. pages 5-8).

In the after final amendment, the Applicant traversed the rejection on the grounds that the cited references do not teach or suggest the independent addition of several stable components of an unstable die to a material in a staining process. The Applicant concludes that the rejection is

based on improper hindsight based on the Applicant's own disclosure. The Examiner does not agree with the Applicant's analysis.

First of all, while the Examiner acknowledges that the art references cited do not explicitly teach or suggest the sequential addition of these components as argued by the Applicant, the law does not require that such a suggestion be explicit in the references. The Federal Circuit has stated that the suggestion to combine references in an obviousness rejection may be shown by "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." In re Fine, 5 U.S.P.Q.2d 1596, at 1598 (1988). In the present case, the knowledge of those in the art suggests the combination resulting the claimed invention.

As indicated above, the art teaches an automated staining device with a built in system for the mixing of the staining reagent. Those in the art are also aware, as indicted by the Applicant's disclosure and by McManus, of the use of unstable dyes, and the making of such from more stable stock solutions. From these teachings, it would be obvious to those in the art to use an automated device wherein the staining reagent being mixed is the result of two or more different components to a known unstable dye, where in the components had been sequentially added to the material. While Copeland teaches that only one staining reagent is applied between washes, the reference does not preclude those in the art from understanding that the stains may be mixed, using the mixing process disclosed by the reference, from sequentially added components that together form the reagent.

However, for the purposes of demonstrating that such would have been obvious to those in the art, the Rejection has been rephrased to include reference to Stokes. This reference is also

concerned with automated methods for the staining of biological samples. Abstract, and col. 10, lines 24-33. The reference also explicitly states that “Where the claims are directed to a step in the staining process, it is understood that the step may comprise a single step where a combination of reagents are applied or sequential steps where more than one reagent or combination of reagents is applied.” Thus, the reference indicates that multiple reagents may be applied as part of single staining step.

It is noted that the Applicant further asserts that there are no teachings that the term “reagent” includes individual ingredients to a stain. This is not found persuasive for two reasons. First, the Stokes reference indicates that multiple reagents may be used in the individual steps in the claimed staining methods. However, in that patent, the claims read on the manipulation of stains, and other reagents. Because the reference indicates that multiple reagents may be involved in the staining step, it clearly implies that multiple reagents may be involved in a single step of staining.

Further, the dictionary meaning of the term “reagent” is represented by Stedman’s Online Medical Dictionary as “Any substance added to a solution of another substance to participate in a chemical reaction.” Further, upon searching the term in the CancerWEB Online medical dictionary, the description indicates that reagents react to form a colored product (a stain). Thus, both the Stokes reference and the dictionary meaning of the term support the Examiner’s interpretation of the term, and lend no credence to the Applicant’s unsupported suggestion that the term “reagent” would not be understood by those in the art to include individual ingredients as well as the final stain product (which reacts with the sample material).

Art Unit: 1648

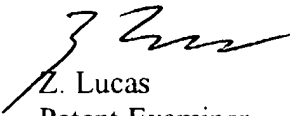
In view of the above, and for the reasons above and in the prior actions, the rejection of claims 1,2, and 4-12 is maintained, and is extended to new claim 13.

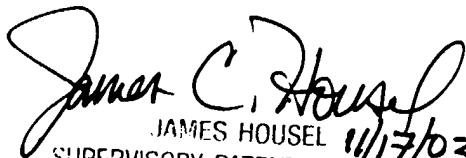
Conclusion

4. No claims are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner


JAMES HOUSEL 11/17/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600